AUG - 5 2003

K 031472

510(k) Summary

Submitter

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035
Contact: Frank Peralta
Date Prepared: May 8, 2003

Device Name

ONE TOUCH® Basic/Profile/ONE TOUCH® II Test Strips
Common name: Glucose test strip

Predicate Device

ONE TOUCH® Basic/Profile/ONE TOUCH® II Test Strips

Device Description

The ONE TOUCH ® Blood Glucose Monitoring System is an *in vitro* diagnostic product consisting of a test strip impregnated with reagents and a reflectance photometer for the determination of glucose in whole blood. Several different ONE TOUCH ® Brand reflectance photometers may be used (the ONE TOUCH ® Basic, ONE TOUCH ® II, or the ONE TOUCH ® Profile Meter). A quality control solution, ancillary devices to aid obtaining a capillary blood sample (lancets and lancing device) as well as data management computer software are also available.

A ONE TOUCH ® Test Strip is inserted into the meter and a drop of blood applied to the test spot. Glucose oxidase present in the test strip catalyzes the reaction of glucose in the sample with oxygen to yield gluconic acid and hydrogen peroxide. Hydrogen peroxide subsequently oxidizes dyes in the test strip in the presence of peroxidase, a second enzyme, to produce a blue colored form of the dyes. The intensity of the blue color produced is proportional to the amount of glucose in the sample. The meter measures the amount of light reflected by the blue product and converts it to a glucose concentration that is presented on the meter display. The user adjusts the meter response for each lot of test strips by entering a calibration code that is specific to that lot into the meter.

No modifications to the intended use or to the fundamental scientific technology of the ONE TOUCH® Blood Glucose Monitoring System are being made. The description above applies to the currently marketed device and will apply equally to the modified device described in this submission.

Intended Use

The ONE TOUCH® Basic/Profile/ONE TOUCH® II Test Strips are intended for use with ONE TOUCH ® Brand meters by healthcare professionals and laypersons with diabetes at home to provide a quantitative measurement of glucose in whole blood as an aid in managing their glycemic state.

Comparison to Predicate Device

The dimensions of the ONE TOUCH® Test Strip have been altered to permit use of a smaller blood drop. The performance of the modified test strip has been shown to be equivalent to that of the predicate through the acceptable hematocrit range (30% to 55%).

Conclusion

The modified ONE TOUCH ®Test Strip is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 5 2003

Mr. Frank Peralta
Senior Regulatory Submissions Specialist
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, California 95035-6312

Re: k031472
Trade/Device Name: One Touch® Basic/Profile/One Touch II Test Strip
Regulation Number: 21 CFR § 862.1345
Regulation Name: System, Test, Blood Glucose, Over-the-Counter
Regulatory Class: II
Product Code: NBW, CGA
Dated: May 8, 2003
Received: May 9, 2003

Dear Mr. Peralta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K031472

Device Name: **ONE TOUCH® Basic/Profile/ ONE TOUCH® II Test Strips**

Indications for Use:

The ONE TOUCH® Basic/Profile/ONE TOUCH® II Test Strips are intended for use with ONE TOUCH ® Brand meters by healthcare professionals and laypersons with diabetes at home to provide a quantitative measurement of glucose in whole blood as an aid in managing their glycemic state.

Division Sign-Off For: Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031472

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)